MAY - 4 2001

K010449

510(k) Premarket Notification Summary

Submitter: Sun Nuclear Corporation
425-A Pineda Court
Melbourne, FL 32940
Phone (321) 259-6862
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Contact: Noel Downey

Date: December 27, 2000

Trade Name: Model 1131 IVD

Common Name: Patient Radiation Dose Monitor

Classification Name: Calibrator, Dose, Radionuclide

Product Code: 90IYI

Substantial Equivalence: PDM #K912249/A, Rainbow #K860469, PC Rainbow #K900932/A

Description and Use:

See Attached

Similarities/Differences with predicate devices:

See Attached

DESRIPTION AND USE

The Sun Nuclear model 1131 IVD (In-Vivo Dosimetry) is a system that measures the radiation output of a linear accelerator or a radioactive substance such as a Co-60 source, during the treatment of a patient. It is expandable from 4 detector inputs up to 28.

The radiation therapist connects the radiation detectors (diodes) to the Detector Module and then positions them on the patient in order to measure the radiation from the accelerator. The battery operated IVD can be used with an accessory Display Module, or a computer. An optically isolated interface allows a PC to be connected during patient contact without possible injury to the patient from any mains leakage.

The therapist leaves the treatment room. Dose measurement is then remotely started on the IVD from the control room using either the accessory Display Module or PC and then the radiation beam is turned on. When the beam turns off, the IVD is stopped and the dose value is displayed. The IVD display value is recorded or printed on an accessory printer. The therapist then enters the room and removes the detector from the patient.

The recorded IVD measurement is a QA test that verifies the dose output during treatment from the radiation machine. The actual treatment plan is calculated in the Treatment Planning Computer (TPC – not part of the IVD) which uses dosimetry data acquired from a NIST traceable calibrated ion chamber and 3D-water phantom. The plan output should also include the "expected" dose at the point of the IVD detector placement. Then the measured IVD dose and the expected TPC dose can be compared for verification. If the expected dose is not verified, the measured dose should not be used to adjust future treatments. Instead, an investigation should be conducted as to why the error occurred. The IVD is calibrated at the institution using the NIST traceable calibrated ion chamber as a standard, the same standard that is used to calibrate the accelerator and the TPC. Therefore, the IVD offers a closed loop QA test of the implementation of the plan.

SIMILARITIES/DIFFERENCES WITH PREDICATE DEVICES:

The following table shows the common functions between the Sun Nuclear Model 1131 IVD and the other three devices (The Nuclear Associates Rainbow and PC Rainbow and the Theta PDM). The function is stated in the left column, and the device column has a "x" if it includes the feature.

Function	IVD	PC Rainbow	Rainbow	PDM
Measure diode radiation detectors	x	x	x	x
Display dose and dose rate in real time	x	x	x	x
Solid state measurement electrometers, microprocessor controlled	x	x	x	x
Electrometer design - unipolar, detector current to pulse count frequency	x	x	x	x
Measurement result printable	x	x	x	x
Selectable calibration configurations for different beams and detectors	x	x	x	x
Dose Alarm set points adjustable by user	x	x	x	x
Calibration storage in non-volatile memory	x	x	x	x
Measurement electrometer in treatment room (eliminates extension cables)	x	x	x	
Detector module expansion capability (add more inputs)	x	x		
Calibration with PC (personal computer) control	x	x		
Password protection of calibration procedures	x	x		
Optical isolation of RS-232 link to PC	x	x		
Spring holder for diode detectors not in use	x	x		
PC storage of measured patient data	x	x		
Suitable for total body treatment measurement	x	x	x	

In addition to the differences noted in the above table, the IVD PC software is written in the Windows environment, whereas the PC Rainbow was a DOS based system. The IVD is battery operated, the PC Rainbow is line operated. The IVD can be expanded to 28 detector inputs, the PC Rainbow limit is 12 inputs.

Sun Nuclear purchased the manufacturing documentation from Theta and manufactured both the PC Rainbow and the PDM. (The PC Rainbow was private labeled for Nuclear Associates.) Sun Nuclear designed the IVD with the same intended use as the PC Rainbow, with a modernization of the electronics, user interface, and patient safety improvement. This essentially improves the performance and technology of the PC Rainbow.

SAFETY AND EFFECTIVENESS SUMMARY
FOR
MODEL 1131 IVD

EFFECTIVENESS

The SNC model 1131 IVD is an effective tool in the radiation oncology department. It offers the ability to perform closed loop quality assurance test of the radiation dose delivery to the patient without a significant burden to the therapist. The IVD can use diode detectors that are already present in the department's inventory; it only requires a calibration with these diodes, this calibration is performed by the physicist using the department's NIST traceable ion chamber as a reference. Because they are so small, the placement of the diode detector is easy for the therapist; and because there is no voltage on the diode detector, there is no electrical shock hazard. The dose measurement result is available instantly, allowing the therapist to compare with the physicist's expected dose and, while the patient is still setup for treatment, notify physics for help in verification if there is an error noted. Since the IVD is not part of the treatment calculation, or the treatment delivery system, it is totally independent and offers an effective method of testing the implementation of the desired treatment. With the operational features of the IVD, there is little effort on the part of the therapist except to: 1) place the detector, 2) select a single button to start the measurement, 3) press the Stop button to get the final answer, 4) compare the measurement to the expected dose, and 5) remove the detector from the patient.

SAFETY FEATURE LIST FOR IVD

	FEATURE	PURPOSE
1.	Battery Operation	Eliminates risk of shock to the patient
2.	Auto shut off during charging	Eliminates risk of shock to the patient
3.	Uses diodes, no detector voltage	Eliminates risk of shock to the patient
4.	Optically isolated serial interface	Eliminates risk of shock to the patient when connected to PC
5.	Energy key calibration	Reduces chance of error by requiring only one key to start
6.	Password protected calibration	Prevents tampering with calibration values
7.	Displays only calibrated detectors	Prevents accidental recording of wrong detector
8.	Diagnostic power up test	Notify user of system error (hardware and software)
9.	User Test button	Allows user to test battery and calibration checksum before use
10.	Low Battery indicator	Cautions user that complete measurement might not be possible
11.	Low Battery shut down	Prevents operation at low battery voltage
12.	Calibration files in IVD and PC	Allows checksum comparison of calibration for validity

SYSTEM DESCRIPTION AND OVERVIEW

The Sun Nuclear model 1131 IVD (In-Vivo Dosimetry) is a system that measures the radiation output of a linear accelerator or a radioactive substance such as a Co-60 source, during the treatment of a patient. The basic system consists of 4 components: Detector Input Module with 4 input connectors, Processor Module, Battery Module, and an A/C Adapter. It is expandable from 4 detector inputs up to 28.

The radiation therapist connects the radiation detectors (diodes) to the Detector Module and then positions them on the patient in order to measure the radiation from the accelerator. At this time, the patient is on the treatment couch of the accelerator, already positioned for treatment, but the beam is not on. The IVD is battery operated for safe patient contact. The IVD uses rechargeable batteries and is not operational when the A/C power adapter is plugged into the Battery Module. The IVD can be used with an accessory Display Module, or a computer. An optically isolated interface allows a PC to be connected during patient contact without possible injury to the patient from any mains leakage.

Typically, a radiation therapy treatment is fractionated into approximately 30 treatment sessions. The purpose of the IVD dose measurement is to verify the dose delivery according to the plan determined by the physicist or dosimetrist. This is best done during the first treatment. If the dose is verified, then subsequent measurements are not performed. If the dose is not verified, then an investigation into the cause of the discrepancy is carried out and the next treatment is measured again with the IVD. This is part of the QA process.

The therapist then leaves the treatment room that is shielded with approximately 3 feet of concrete and a heavy interlocked door. Dose measurement is then remotely started on the IVD from the control room using either the accessory Display Module or PC and then the radiation beam is turned on. A treatment fraction generally lasts for ½ minute or so. When the beam turns off, the IVD is stopped and the dose value is displayed. The IVD display value is recorded or printed on an accessory printer. The therapist then enters the room and removes the detector from the patient.

Password protection allows only the physicist to setup and calibrate the IVD. The physicist selects units (Rad or Gy) and display formats, connects detectors to the inputs, and calibrates the IVD buttons using selected detectors in the specific radiation beams. During a treatment session, when the therapist presses a calibrated button, the IVD software records and displays data from only the detectors calibrated with that button. The calibration information is stored in the IVD computer file and the IVD instrument itself and can be reviewed by the physicist at any time.

The recorded IVD measurement is a QA test that verifies the dose output during treatment from the radiation machine. The actual treatment plan is calculated in the Treatment Planning Computer (TPC – not part of the IVD) which uses dosimetry data acquired from a NIST traceable calibrated ion chamber and 3D-water phantom. The plan output should also include the "expected" dose at the point of the IVD detector placement. Then the measured IVD dose and the expected TPC dose can be compared for verification. If the expected dose is not verified, the measured dose should not be used to adjust future treatments. Instead, an investigation should be conducted as to why the error occurred. The IVD is calibrated at the institution using the NIST traceable calibrated ion chamber as a standard, the same standard that is used to calibrate the accelerator and the TPC. Therefore, the IVD offers a closed loop QA test of the implementation of the plan.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2001

Mr. Noel Downey
Sun Nuclear Corp.
425-A Pineda Court
MELBOURNE FL 32940

Re: K010449
IVD (IN VIVO DOSIMETER), MODEL 1131
Dated: February 5, 2001
Received: February 15, 2001
Regulatory Class: II
21 CFR §892.5050/Procode: 90 IYE

Dear Mr. Downey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(K) Number (if known): K 010499

Device Name: Sun Nuclear Corporation Model 1131 IVD

Indications for Use:

Sun Nuclear's Model 1131 IVD (In Vivo Dosimeter) is a battery operated dosimetry system designed to measure the patient's dose during radiation therapy treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010449

Prescription Use √ **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)